

**Appl. No.** : **09/646,950**  
**Filed** : **December 8, 2000**

#### **AMENDMENTS TO THE DRAWINGS**

Formal drawings are submitted herewith. Figures 4 and 5 have been deleted and have been incorporated in the specification because these figures merely include chemical structures. Accordingly, the formal drawings are now renumbered Figures 1-7.

The formal drawings address the objections to the figures in the Notice of Draftsperson's Patent Drawing Review sent with the Office Action of October 2, 2003.

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### REMARKS

Claim 1 has been amended. As a result, Claims 1-4, 8-20, 38-42, and 52-61 remain pending in the present application. Support for the amendments is found in the specification and claims as filed. Accordingly, the amendments do not constitute the addition of new matter. Reconsideration of the application in view of the foregoing amendments and following comments is respectfully requested.

#### Substitute Specification

The Applicant has amended the specification to include the priority claim. No petition is believed to be necessary to introduce this amendment because the priority claim was properly made during the international phase of this application. However, should any fees be necessary for entry of this amendment, please charge them to our deposit account as instructed at the end of this Communication.

The specification has been amended to incorporate originally-filed figures that simply contain chemical structures. Accordingly, the Applicant has added no new matter by entry of the attached substitute specification.

#### Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected Claims 1-4, 8, 9, 11, 13-17, 19, 38-42, and 56-60 under 35 U.S.C. § 112, first paragraph, because the Examiner believes that the claims are overly broad as to encompass both down-regulation and up-regulation when the specification discloses compounds or agents that inhibit or down-regulate a response.

The Examiner indicated that the specification is enabling for a method of inhibiting an immune response in a patient. As amended, Claim 1 recites “[a] method of suppressing or inhibiting the immune response in a patient in need of such modulation.”

The Examiner also believes that the claims read upon the use of any inhibitor of asparaginyl endopeptidase, while the specification fails to disclose other types of compounds or agents and does not teach the artisan how to make or how to use any of them.

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As amended, Claim 1 recites, “an effective amount of a competitive inhibitor of asparaginyl endopeptidase, wherein the competitive inhibitor is a peptide comprising an asparagine-containing peptide.”

Support for the amendment can be found in the specification. The specification at Paragraph [0029] discloses that a competitive inhibitor is a peptide or peptide derivative comprising an asparagine-containing peptide, and at Paragraph [0037], discloses methods of making the peptides. Further, the specification at Paragraph [0039] discloses peptide derivatives. Such peptide derivatives presumably can be made with conventional procedures known to an artisan. Accordingly, amended Claim 1 is fully enabled by the specification.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. § 102

The Examiner rejected Claims 1, 9-12, 15-20, 38, and 39 under 35 U.S.C. § 102(b) as being anticipated by Manoury et al. (*Nature* [1998] 396:695-699).

According to M.P.E.P.716.02(b), “[a] rejection based on 35 U.S.C. § 102(b) can be overcome by:...(C) Perfecting priority under 35 U.S.C. 119(e) or 120 >, within the time periods set in 37 CFR 1.78(a) or filing a grantable petition under 37 CFR 1.78(a), < by amending the specification of the application to contain a specific reference to a prior application or by filing an application data sheet under 37 CFR 1.76 which contains a specific reference to a prior application in accordance with 37 CFR 1.78(a)>, and by establishing that the prior application satisfies the enablement and written description requirements of 35 U.S.C. 112, first paragraph.”

Manoury et al. was published on December 17, 1998, while the present application has an effective filing date of March 26, 1998. The specification has been amended to include the priority claim. Also, a copy of the priority application that shows the presently-pending claims being supported by the priority document is submitted herewith. Since the priority claim cites GB 9806442.1, filed March 26, 1998, Manoury et al. with a publication date of December 17, 1998, does not qualify as prior art.

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Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 102(b).

CONCLUSION

In view of the foregoing amendments and comments, it is respectfully submitted that the present application is fully in condition for allowance, and such action is earnestly solicited.

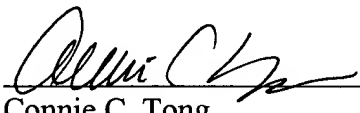
The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 17, 2005

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